

## **Remarks**

Claims 1, 2 and 7 – 16 are pending. Claim 16 is hereby cancelled. No claims are added or amended. Reconsideration of the rejections is respectfully requested.

### **I. Rejection under Section 103 –Carson in view of Helland**

Claims 1, 2 and 7 - 10 stand rejected under 35 U.S.C. Section 103 as being obvious over Carson (US 5,931,862) in view of Helland (US 5,466,254). This rejection is again respectfully traversed.

Applicant's previous arguments are of record and Applicants stand by them. The Examiner may refer to them if desired. They are not reproduced herein.

In the Final Office Action, the Examiner responds to the Applicants' previous amendments as set forth below. The Attorney for Applicants is not entirely sure what issues the Examiner is addressing by these arguments, but understands that the Examiner is advancing these arguments as the basis for maintaining the Section 103 rejection. Because the arguments make no sense, it follows that any rejection that depends upon them corresponding fails.

The Examiner's arguments include the following statements, reproduced from the Final Office Action:

Carson discloses that the porous layer is adapted to prevent chronic tissue ingrowth (column 2, lines 47-48). The prevention of chronic tissue ingrowth, which prevents the electrode from coming in direct contact with the tissue, is a sufficient and effective means of preventing the electrode from stimulating tissue in proximity to the electrode. Alternatively, the pulse generator (Fig. 1, generator 11) of Carson must inherently contain a control means used in the art, such as a microprocessor. That control means provides a means for preventing the second electrode from stimulating the tissue as the alternate state to control-driven stimulation of tissue. If the device is off, or the second electrode channel is powered down or in a blanked state, the control means is preventing the second electrode from delivering stimulation to the tissue. However,

The Examiner's above statements are respectfully asserted to defy common sense and therefore the rejection under Section 103 which expressly relies upon these statements is respectfully asserted to be per-se improper.

First, the statement that prevention of chronic tissue ingrowth as disclosed in Carson acts to prevent the electrode from stimulating cardiac tissue is flatly erroneous for two reasons.

a). The express purpose of the coating in Carson is to enhance the ability of the electrode to stimulate tissue, not to prevent it. (See Carson's Abstract)

b) The stated purpose of preventing ingrowth of tissue in Carson is to improve stimulation characteristics. The tissue that the coating in Carson is intended to keep out is fibrotic tissue (non-stimulable tissue), as would be appreciated by one of skill in the art. The conductive materials within the Carson coating accomplish improved stimulation characteristics by having superior conduction capability to fibrotic tissue.

The examiner's above statements are also understood to underlie the argument below that combining Carson with Helland produces the invention.

Withdrawal of the Section 103 rejection is again respectfully requested for this reason.

Second, the presence of a microprocessor in Carson is entirely irrelevant to claim 1 which claims a porous coating on the lead, not a device in the pulse generator. Because the statement is irrelevant to the claims, it defies common sense that the Section 103 rejection could properly be based upon this statement.

Withdrawal of the Section 103 rejection is respectfully requested for this reason as well

The Final Office Action continues as set forth below:

Carson does not disclose that the first and second electrodes are located on first and second separate lead bodies, wherein the first lead/electrode is placed in a cardiac vein and the second lead/electrode is placed in the right ventricle. Helland teaches a multi-

lead cardiac pacing system (Fig. 7, Abstract) wherein each lead 150, 120, 148, 160 has a separate connector 130, 132, and wherein the first lead/electrode is placed in a cardiac vein 30 and the second lead/electrode is placed in the right ventricle 154, wherein the first and second leads act as the anode and cathode in a bipolar pacing system (Col. 5, Lines 50-67). It would have been obvious to one having ordinary skill in the art at the time of the invention to use separate leads for the separate electrodes, as taught by Helland et al, in the bipolar pacing system with electrode porous layer as disclosed by Carson, in order to allow for implantation in both the cardiac vein and the right ventricle for pacing/defibrillation therapy.

The problem with this argument is that the cardiac vein electrode in Helland is expressly disclosed as covered with a coating to enhance its stimulation capabilities. The Examiner takes the position that Helland does not anticipate the claims without Carson's coating. The Examiner has also taken the

position that the coating of Carson impairs its stimulation capabilities. According to the Examiner's own argument, therefore, the coatings on the electrodes of Carson and Helland accomplish opposite results. As such, substitution of the coating of Carson (as interpreted by the Examiner) for that of Helland would be contrary to the express teaching of Helland.

Again, the Examiner's arguments defy common sense and the Section 103 rejection relying on these arguments is respectfully asserted to be improper.

### **III. Rejections under Section 103 –Carson in view of Helland and Hull or Soukup**

Claims 11 - 15 and 16 stand rejected under 35 U.S.C. Section 103 as being obvious over Carson (US 5,931,862) in view of Helland (US 5,466,254) in view of Hull, et al. (US 5,269,810) or Soukup, et al (US 5,466,252). This rejection is respectfully traversed.

These rejections all depend upon the erroneous rejection of claim 1 as discussed above. Withdrawal of these rejections is correspondingly requested.

### **Conclusion**

Applicants again respectfully assert that the present claims are in condition for allowance. Withdrawal of the instant rejections and issuance of a Notice of Allowance is respectfully requested.

The remarks presented herein are believed fully responsive to the Office Action and are believed sufficient to overcome the rejections presented in the Office Action. However, there may be other arguments to be made as to why the pending claims are patentable. Applicant does not concede any such arguments by having not presented them herein. Finally, please grant any extension of

time, if necessary for entry of this paper, and charge any fee due for such extension or any other fee required in connection with this paper to Deposit Account No. 13-2546.

Should any issues remain outstanding, the Examiner is urged to telephone the undersigned to expedite prosecution. The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 13-2546.

Respectfully submitted,

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Date

/Reed A. Duthler/  
Reed A. Duthler  
Reg. No. 30, 626  
(763) 526-1564  
Customer No. 27581